The applicant argues that the claims as filed do not constitute distinct and independent inventions. The following claims represent the independent claims at issue.

1. A liquid oral pharmaceutical composition, comprising:
(a) a proton pump inhibitor; and
(b) at least one buffering agent;
wherein if said proton pump inhibitor is omeprazole, it must be present in a concentration greater than 1.2 mg/ml, and if said inhibitor is lansoprazole, it must be present in a concentration greater than 0.3 mg/ml.

6. A liquid oral pharmaceutical composition, comprising:
(a) a proton pump inhibitor; and
(b) at least one buffering agent;
wherein said proton pump inhibitor is selected from the group consisting of omeprazole (in a concentration greater than 1.2 mg/ml), lansoprazole (in a concentration greater than 0.3 mg/ml), pantoprazole, rabeprazole, dontoprazole, perprazole, habeprazole, ransoprazole, pariprazole, and leminoprazole.

7. A solid oral pharmaceutical composition, comprising:
(a) a proton pump inhibitor; and
(b)at least one buffering agent;
wherein said composition is in a dosage form selected from the group consisting of a powder, a tablet, a suspension tablet, a chewable tablet, a capsule, an effervescent powder, an effervescent tablet, pellets and granules, and wherein said dosage form is not enteric coated or time-released.

15. A method of treating gastric acid disorders comprising
(a) administering to a patient an oral pharmaceutical composition comprising a proton pump inhibitor and
(b) [administering] at least one buffering agent
wherein said administering step comprises providing a patient with a single dose of the pharmaceutical composition without requiring further administration of the at least one buffering agent.

16. A kit for the preparation of a liquid oral pharmaceutical composition, comprising:
(a) a powder comprising a proton pump inhibitor; and
(b) a liquid buffering agent to be mixed with said powder to form said liquid composition.

17. A kit for the preparation of a liquid oral pharmaceutical composition, comprising
(a) a proton pump inhibitor in combination with at least one buffering agent, said combination in a dry form, and
(b) a diluent to be mixed with said dry form to create said composition.

18. An oral pharmaceutical composition to be administered in combination with a proton pump inhibitor, comprising
(a) at least one buffering agent,

(b) wherein said composition is in a dosage form selected from the group consisting of a powder, a tablet, a chewable tablet, a capsule, an effervescent powder, an effervescent tablet, pellets and granules, and wherein said dosage form is not enteric coated or time-released.

21. A method for enhancing the pharmacological activity of a proton pump inhibitor intravenously administered to a patient, comprising

(a) orally administering to the patient at least one parietal cell activator at a time interval selected from the group consisting of before, during and after the intravenous administration of the proton pump inhibitor.

First, claim 1 and 15 call for a product and a method of using that product. Claim 1 calls for an unspecified proton pump inhibitor (PPI) in combination with at least one buffering agent. The claim does not call for a specific PPI and is not in any way so limited. The applicant further notes that the claim does not attempt to claim strictly a PPI. Rather the claimed invention relates to a generic PPI in a liquid oral composition plus a buffer. Claim 15 (the method claim) includes the method of using the composition of claim 1. Since the method of using the product incorporates the composition of claim 1, it is improper to separate the product claims from the method of use claims. See MPEP 806.05(h).

By analogy, the applicant argues that if Examiner thinks as each PPI separately and is restrictable merely because the chemical compositions are different, then logically, all subspecies in a Markush group would be restricted out. For example, an application claiming R-X, wherein X is a halogen, would then be subject to restriction because R-Cl, is different from R-I, which is different from R-F, which is different from R-Br. This would belie the expressed purpose of Markush claiming a genus. See, MPEP 2173.05(h). In this particular case, it is clear that the genus is the group of Proton Pump Inhibitors. See generally, MPEP 803.02 (Restriction practice of Markush Groups). This section of the MPEP states that restriction of the species within a Markush Group is proper only when there is no true generic claim or when the species are so large in number that constitutes an undue burden. The applicant argues that there is a generic

claim across all claims in question and that the number of PPI's is not undue since the classification search would reveal all PPI's.

Second. Group II does not attempt to claim any composition that is separate, distinct, and independent from the claims of Group I. As mentioned above, the independent claims do not claim a specific PPI, but rather claim a buffered PPI. While it is true that the individual PPI's are structurally distinct (as they must be otherwise they would be the same molecule), claim 1 and 15 are linking claims across all individual PPI's. If the Examiner concludes that the mere fact that the presence a specific PPI within a genus makes it independent, than this would require that any patent attempting to include a Markush group claim would necessarily require restriction since each species within the Markush group is uniquely structurally different by definition. Accordingly, claim 1 is generic across all PPI's because to hold otherwise would mean that a separate patent is necessary for each individual PPI. The Examiner has the burden of proving of proving that each individual PPI is independent and distinct enough to impose a restriction. The applicant respectfully suggests that she has not done so. See, MPEP 806.05(h).

The applicant also notes that merely because a particular composition may be found in two classes, does not ipso facto make restriction necessary. The applicant notes that Classes 424 and 514 cover identical subject matters, even to the extent that the Manual of Classification states that the contents of class 514 are within class 424. Therefore, a search of class 424 will search class 514 also. Therefore, no undue or serious burden is placed on the Examiner in the search. MPEP 803. The applicant notes that this section states that, assuming arguendo, that the patent application includes distinct and independent inventions, then the application as a whole should still be examined and no restriction is necessary if no substantial burden is placed on the Examiner.

The applicant also notes that a dependent claim includes a parietal cell activator. However, the presence of a dependent claim covering an activator does not render the claims subject to restriction. As noted above, the activators or potentiators do add synergistic effect, but that does not mean that the claims present independent and distinct inventions. The definition of independent means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. MPEP 802.01. In the present case, the activators are common in effect as they provide synergistic effect to the buffered PPI. They are similar in effect because they can be parietal cell activators. Accordingly, they are not independent. Merely because they may be different chemicals does not make them independent per se, subject to restriction for placing an undue burden on the Examiner.

Claims 16 and 17 call for kit claims. However, as noted above, that the purported class of Class 424 does not make it independent since Classes 514 and 424 comprise the same subject matter. Furthermore, claims 16 and 17 include some of the same products as claimed in other independent claims. For example, claims 16 and 17 also call for, among other things, a buffered PPI. Therefore, the applicant suggests that claims 16 and 17 are not distinct and independent enough, and fail to impose an undue burden on the Examiner, sufficient to warrant restriction.

Similarly, claims 21 and 22 do not represent a significant variation on the other method claims in that claims 21 and 22 do not represent independent and distinct inventions and do not impose an undue burden on the Examiner sufficient to warrant restriction.

Finally, the applicant notes that while the Examiner states that the inventions have acquired status in the art because of their recognized divergent subject matter, this is a conclusion. The Examiner has not provided sufficient proof to discharge her burden of showing independence and distinctness.